

Translation

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

10/529454

(PCT Article 36 and Rule 70)

| | | | |
|---|--|--|--|
| Applicant's or agent's file reference IEC03003PCT | | FOR FURTHER ACTION See Form PCT/IPEA/416 | |
| International application No. PCT/CN03/00838 | International filing date (day/month/year) 29 SEP 2003 (09.09.03) | Priority date (day/month/year) 29 SEP 2002 (29.09.02) | |
| International Patent Classification (IPC) or national classification and IPC IPC ⁷ : A61K31/41, 31/395, 9/24, A61P35/00 | | | |
| Applicant Tianjin TASLY Group Co., LTD ET.AL | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | |
| Date of submission of the demand 01.APR.2004(01.04.04) | | Date of completion of this report 25.JAN.2005(25.01.05) | |
| Name and mailing address of the IPEA/ 6 Xitucheng Rd., Jimen Bridge, Haidian District, 100088 Beijing, China | | Authorized officer WANG Jingjing | |
| Facsimile No. 86-10-62019451 | | Telephone No. 86-10-62085257 | |



INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN03/00838

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished

- ☐ the description:

pages _____ as originally filed/furnished
pages * _____ received by this Authority on _____
pages * _____ received by this Authority on _____

- ☐ the claims:

pages _____ as originally filed/furnished
pages * _____ as amended (together with any statement) under Article 19
pages * _____ received by this Authority on _____
pages * _____ received by this Authority on _____

- ☐ the drawings:

pages _____ as originally filed/furnished
pages * _____ received by this Authority on _____
pages * _____ received by this Authority on _____

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/CN03/00838**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement:**

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-14 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-14 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-14 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

D1: CN1345240A

D2: CN1156400A

D3: WO0217971A1

D1 discloses the use of temozolomide for cancer treatment. D2 discloses a sustained release system containing hydromorphone, a compound used for pain relief in the treatment of cancer. D3 discloses a controlled release system. The prior art neither discloses the same controlled release system as the invention, nor teaches the skilled in the art to obtain the said system. Thus, the novelty and inventiveness of the invention can be acknowledged. Furthermore, the invention is industrial applicable. Thus, Claims 1-14 all meet the requirements of PCT Art.33(1),(2) and (3).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/CN03/00838

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

| Application No. Patent No. | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (valid claim) (day/month/year) |
|-------------------------------|--------------------------------------|---------------------------------|---|
| CN1345240A | 17.04.02 | 27.03.00 | 30.03.99 |
| CN1156400A | 06.08.97 | 20.06.95 | 23.06.94 |
| WO0217971A1 | 07.03.02 | 03.09.01 | 01.09.00 |

2. Non-written disclosures (Rule 70.9)

| Kind of non-written disclosure | Date of non-written disclosure (day/month/year) | Date of written disclosure referring to non-written disclosure (day/month/year) |
|--------------------------------|--|---|
| | | |

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专利合作条约

PCT

REC'D 24 FEB 2005

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10/529454

专利性国际初步报告

(PCT 第II章)


(PCT 36 和细则 70)

| | | |
|--|--|---------------------------------------|
| 申请人或代理人的档案号 IEC03003PCT | 关于后续行为 参见 PCT/IPEA/416 表 | |
| 国际申请号 PCT/CN03/00838 | 国际申请日(日/月/年) 29.9 月 2003 (09.09.03) | 优先权日(日/月/年) 29.09 月 2002(29.09.02) |
| 国际专利分类(IPC)或者国家分类和 IPC 两种分类 IPC ⁷ : A61K31/41,31/395,9/24, A61P35/00 | | |
| 申请人 天津天士力集团有限公司 等 | | |

1. 本报告是国际初步审查单位根据条约 35 做出的国际初步审查报告,并依照条约 36 将其传送给申请人。
2. 本报告共计 4 页,包括扉页。
3. ☐ 本报告还有附件,
 - a. ☐ (传送给国际局和申请人)共计 ____ 页,包含
☐ 修改后的并且作为本报告基础的说明书修改页、权利要求书修改页和/或附图修改页,和/或对
 本国际初步审查单位所做出的更正页(见 PCT 细则 70.16 和行政规程 607)。
☐ 国际初步审查单位认为修改超出原始公开范围的废除页,参见第 I 栏第 4 项和补充栏。
 - b. ☐ (传送给国际局)共计 (指明电子载体的类型和数量) ____, 包含有在与序列列表有关的补充栏中
 指明的计算机可读形式的序列列表和/或与其相关的表格。(行政规程 802)

3. 本报告包括关于下列各项的内容:

- I ☒ 报告的基础
- II ☐ 优先权
- III ☐ 不做出关于新颖性、创造性和工业实用性的意见
- IV ☐ 缺乏发明的单一性
- V ☒ 按条约 35(2)关于新颖性、创造性或工业实用性的推断性意见;支持这种意见的引证和解释
- VI ☒ 引用的某些文件
- VII ☐ 国际申请中的某些缺陷
- VIII ☐ 对国际申请的某些意见

| | |
|--|--|
| 提交要求书的日期 01.4 月.2004(01.04.04) | 完成本报告的日期 25.1 月/2005(25.01.05) |
| 中华人民共和国国家知识产权局 IPEA/CN 中国北京市海淀区西土城路 6 号(100088) 传真号: (86-10)62019451 | 授权官员 王晶晶 电话号码 (86-10)62085257  |

I. 报告的基础

1. 关于所使用的语言, 除本项下另有说明外, 本书面意见基于的语言为提交本国际申请时所使用的语言。

☐ 本书面意见基于原始语言的使用后述语言之译文 _____,

这种语言是

☐ 为了国际检索而提交的译文所使用的语言(细则 12.3 和 23.1 (b))。

☐ 为了国际申请的公布而提交的译文所使用的语言(细则 12.4)。

☐ 为了国际初步审查而提交的译文所使用的语言(细则 55.2 和/或 55.3)。

2. 关于国际申请中各个部分, 本报告基于(申请人为答复受理局根据条约 14 所发通知而提交的替换页, 在本报告中视为“原始提交”的文件, 不作为本报告的附件)

☒ 原始提交的国际申请。

☐ 说明书, 第 _____ 页 原始提交的, _____ 初审单位收到的, _____ 初审单位收到的。

☐ 权利要求, 第 _____ 页, 原始提交的, _____ 初审单位收到的, _____ 初审单位收到的。

☐ 附图, 第 _____ 页, 原始提交的, _____ 初审单位收到的, _____ 初审单位收到的。

☐ 序列表和/或相关表格——参见与序列表有关的补充栏。

3. 修改导致以下内容的删除:

☐ 说明书, 第 _____ 页

☐ 权利要求, 第 _____ 项

☐ 附图, 第 _____ 页, 图 _____

☐ 序列表(具体说明) _____

☐ 与序列表相关的表格(具体说明) _____

4. ☐ 由于本报告附件的(某些)修改, 如下所列, 被认为超出了原始公开的范围, 如补充栏所示, 因此本报告是按照没有修改的情况做出的(细则 70.2(c))。

☐ 说明书, 第 _____ 页

☐ 权利要求, 第 _____ 项

☐ 附图, 第 _____ 页, 图 _____

☐ 序列表(具体说明) _____

☐ 与序列表相关的表格(具体说明) _____

*如果第 4 项适用, 一些或全部的文件页可能做出“废除”标记。

V. 按条约 35 (2) 关于新颖性、创造性或工业实用性的推断性意见；支持这种意见的引证和解释

1. 意见

| | | |
|-----------|-----------|---|
| 新颖性(N) | 权利要求 1-14 | 是 |
| | 权利要求 | 否 |
| 创造性(IS) | 权利要求 1-14 | 是 |
| | 权利要求 | 否 |
| 工业实用性(IA) | 权利要求 1-14 | 是 |
| | 权利要求 | 否 |

2. 引证和解释 (细则 70.7)

对比文件 1: CN1345240A

对比文件 2: CN1156400A

对比文件 3: WO0217971A1

对比文件 1 公开了使用替莫唑胺治疗癌症病人的方法。对比文件 2 公开了癌症治疗中使用的氢化吗啡酮的皮下缓释给药装置。对比文件 3 公开了一种缓释给药系统。现有技术中没有记载与本发明相同的替莫唑胺的控释给药系统，并且从现有技术中也没有启示可以教导本领域技术人员获得本发明的技术方案。因此本发明具有新颖性以及创造性，符合 PCT 条约第 33 条(2)、(3)款项的规定。此外，本申请权利要求 1-14 也符合 PCT 条约第 33 条(1)所要求的工业实用性。

VI. 某些引用文件

1. 某些已公布的文件(细则 70.10)

| 申请号 专利号 | 公布日 (日/月/年) | 申请日 (日/月/年) | 优先权日(有效的) (日/月/年) |
|-------------|----------------|----------------|----------------------|
| CN1345240A | 17.04.02 | 27.03.00 | 30.03.99 |
| CN1156400A | 06.08.97 | 20.06.95 | 23.06.94 |
| WO0217971A1 | 07.03.02 | 03.09.01 | 01.09.00 |

2. 非书面公开(细则 70.9)

| 非书面公开的种类 | 非书面公开的日期 (日/月/年) | 述及非书面公开的 书面公开的日期 (日/月/年) |
|----------|---------------------|--------------------------------|
|----------|---------------------|--------------------------------|